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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,566	09/14/2001	Naoki Tsuchiya	Q66152	8705

7590

06/08/2005

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EXAMINER

STOCKTON, LAURA

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,566

Applicant(s)

TSUCHIYA ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-28 is/are allowed.
- 6) ☒ Claim(s) 29-33 and 35-40 is/are rejected.
- 7) ☒ Claim(s) 34, 41 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/28/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 22-42 are pending in the application.

Election/Restrictions

Newly submitted (amended) claims 41 and 42 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: currently amended claims 41 and 42 are directed to preventing or treating a number of patentably distinct diseases in addition to the examined method of use found in instant claim 22. Further, the various processes of use are also patentably distinct because the processes for using the product as claimed can be practiced with other materially different products. Additionally, since the application is a 371 application, if an application contains claims to more than one of the combinations of categories of invention, unity of invention is not present.

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Since applicant has received a number of actions on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, methods of use not embraced by the method of instant claim 22 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections and objections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections and objections will not be addressed.

Information Disclosure Statement

The information disclosure statement filed

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March 28, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Therefore, only the U.S. patents, WO 00/03997 and its EP family member (EP 1,097,926) have been considered.

Further, in the cover letter of the Information Disclosure Statement, Applicants state that attached is a PTO/SB/08 A & B form and a copy of a Communication from the Hungarian Patent Office. However, no such documents were found.

Terminal Disclaimer

The terminal disclaimer filed on March 29, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the

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expiration date of any patent resulting from 09/743,483 has been reviewed and is accepted. The terminal disclaimer has been recorded. However, it is noted that 09/743,483 was abandoned on March 23, 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-33 and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bru-Magniez et al. {U.S. Pat. 5,021,443}, Bru-Magniez et al. {U.S. Pat. 5,124,336} and Bru-Magniez et al. {U.S. Pat. 5,128,359}, each in combination with Chakravarty et al. {U.S. Pat. 5,128,327}.

Determination of the scope and content of the prior art (MPEP

§2141.01)

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Applicants claim benzimidazole products. Bru-Magniez et al. '443 (columns 1, 2 and 11; or Example 63 in column 29), Bru-Magniez et al. '336 (columns 1, 2, 11 and 12; or Example 59 in column 41) and Bru-Magniez et al. '359 (columns 1, 2, 11 and 12 ; or Example 64 in column 41) each teach benzimidazole products, that are structurally similar to the instant claimed products, which are useful in treating heart failure.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between the compounds of Bru-Magniez et al. '443, Bru-Magniez et al. '336 and Bru-Magniez et al. '359 and the instant claimed compounds is that the compounds in instant independent claim 29 require where M is a sulfinyl or sulfonyl group and the prior art teaches sulfur. Or in the case of instant independent claim 31, X¹ and X² must represent substituents such as -CH₂NH₂, -CONR¹R², etc., in which Bru-Magniez et al.

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'443, Bru-Magniez et al. '336 and Bru-Magniez et al.

'359 do not teach.

However, Chakravarty et al. teach the interchangeability of sulfur, sulfonyl and sulfonyl {see variable E, definition b)} in column 4, line 38 in benzimidazole compounds (column 2) that are useful in treating, for example, heart failure (column 1, lines 63-68; and column 2, lines 1-5). Further, Chakravarty et al. teach the interchangeability of the benzimidazole core being unsubstituted or substituted with substituents such as alkyl, $-\text{NO}_2$, $-\text{CH}_2\text{NH}_2$, $-\text{COOH}$, COOalkyl and $-\text{CONH}_2$ (see the definitions of $-\text{A}^1-\text{A}^2-\text{A}^3-\text{A}^4-$ and of the R^4 variable in columns 3-5).

***Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)***

One skilled in the art would thus be motivated to prepare compounds embraced by Bru-Magniez et al. '443, Bru-Magniez et al. '336 and Bru-Magniez et al. '359, especially in view of the teachings in Chakravarty et

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al., to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds that would be useful in treating diseases/disorders such as heart failure. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicants' arguments filed March 29, 2005 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 22-28 are allowed over the art of record.

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Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 41 and 42 are objected to for containing non-elected subject matter.

Conclusion

Applicants' submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on March 28, 2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first

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reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

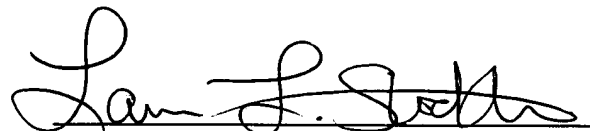
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private

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PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

June 6, 2005